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November 9, 2020

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on November 11, 2020.

1. Deposition Protocol

In accordance with the Court's order on October 30, 2020 (Dkt. 611), the parties have added provisions to the Deposition Protocol to include requirements that (1) the person(s) who will appear in response to a Fed. R. Civ. P. 30(b)(6) deposition notice shall be identified at least fourteen days before the first date the deposition is scheduled (*see* Deposition Protocol § E.3), and (2) the lead questioner

and attorney defending the deposition shall be identified as soon as practicable but no later than fourteen days before the first date the deposition is scheduled (*see id.* § B.1).

Since the October 28 conference, the parties have met and conferred twice on the issues remaining with respect to the Deposition Protocol in an effort to finalize the document. Nevertheless, the parties were unable to resolve all disputes. A copy highlighting the unresolved issues is attached hereto as **Ex. A**.

In light of the Court's order that all disputes not raised before November 11, 2020 with respect to finalizing the parties' general Deposition Protocol shall be deemed waived, Defendants identify the remaining issues as follows:

First, during the last conference with the Court, Your Honor acknowledged that Defendants' proposal that the parties include language in the Deposition Protocol to avoid burdening witnesses deposed pursuant to the valsartan Master Complaint with having to provide duplicative testimony on overlapping issues raised in depositions pursuant to Master Complaints filed based on irbesartan or losartan. As the Court noted, "in concept, isn't that [suggestion] hard to dispute[?]" (*id.* at 19:12-13), "we certainly don't have to spend the first hour or two at the [losartan/irbesartan] deposition going over the [valsartan] gentleman's work history or employment history and educational background," (*id.* at 21: 12-17) and "it's hard

to disagree with the general notion that there are going to be specific questions regarding losartan, for example, that are not applicable to [v]alsartan." (*id.* at 22:20-23). The Court "defer[red] this issue for the moment [to] let the parties discuss it further" and stated, "maybe, maybe not, we'll have to address it in the future." *Id.* at 22-23. Since the conference, Plaintiffs have maintained the protocol should not include anything regarding irbesartan and/or losartan. Defendants believe the following language, which is consistent with the Court's statements on October 28, 2020, should be included in the Deposition Protocol:

> To avoid burdening witnesses with multiple depositions, the parties agree that in scheduling depositions noticed pursuant to master complaints filed with respect to Irbesartan and/or Losartan the parties will work together to limit those depositions to avoid questioning on topics/issues that overlap with topics/issues that are the subject of the deposition noticed pursuant to the valsartan master complaint.

Second, notwithstanding having first served a draft of the Deposition Protocol in July 2020, which was based on the *Benicar* deposition protocol, and despite months of exchanging drafts, since the conference with the Court on October 28, 2020, Plaintiffs proposed three new edits to the Deposition Protocol, which are unnecessary: (1) "the parties shall give their best efforts to proceed as scheduled" (*see* Deposition Protocol § D); (2) attendance at depositions should be subject to "space limitations" (*see* Deposition Protocol § F.1; *but see* § F.2); and (3) "the

suspension of a deposition should occur only as a last resort" should be included (*see* Deposition Protocol § H.3(a)).

The proposal that the parties use "best efforts" to keep the schedule and the depositions may only be suspended as a "last resort" are unnecessary additions given the Court's good cause standard for evaluating disputes, which has been routinely applied in this litigation. The suggestion that deposition attendance be predicated upon whether there is sufficient space contradicts the Court's clear pronouncement at the last conference that all of the Defendants have the right to attend a deposition. *See* Tr. of 10-28-20 Hrg. at 26:6-8 ("Well, that issue is resolved. Everybody can attend the depositions."). Defendants are concerned that Plaintiffs' proposed language could be used to preclude Defendants from attending depositions of treating physicians and other witnesses, who might attempt to have their depositions conducted in a small office. Defendants' offices have sufficient space to accommodate those who have the right to attend a deposition.

Third, since the last case management conference, Plaintiffs have proposed that the percentage of time should be increased for depositions that require translation services (*see* Deposition Protocol § G.1) by 75%. However, Defendants previously proposed that such time be extended by 50% in the foreign national addendums to the Deposition Protocol. Defendants propose the Court defer ruling

on this issue until the parties negotiate the foreign national addendums, as this issue is most pertinent to those witnesses, as Defendants' foreign employees, in particular ZHP, are the witnesses who will be most likely need a translator.

2. <u>The Rule 34 Document Requests to Class Representatives</u>

(a) The Rule 34 Document Requests to the Individual Consumer Economic Loss Class Representatives Should be Approved

The parties have had multiple communications and productive meet and confers and have reached agreement as to the Rule 34 requests to be served on the individual consumer putative economic loss class representatives. Defendants request that the Court issue an order approving these requests, attached as **Ex. B** hereto, and ordering all individual consumer putative economic loss class representatives to respond without objection and produce documents within 30 days of the Court's order.

(b) Defendants' Rule 34 Document Requests to the Medical Monitoring Class Representatives Should be Approved and the Depositions of These Plaintiffs Should Not Lag Behind Those of the Economic Loss Class Representatives

The parties also have met and conferred and reached agreement as to the Rule 34 requests to be served on the putative medical monitoring class representatives, which in large part are the same as the agreed upon requests to the individual consumer economic loss class representatives. During the meet and confer, Plaintiffs

raised no objections to any of the requests that are the same as those to be served on the economic loss class representatives. As to the few requests tailored to the medical monitoring specific allegations, the parties' negotiations have focused on two issues related to one request—Request No. 5.

Plaintiffs objected to Defendants' original draft of Request No. 5 on the basis of overbreadth of (1) subject matter and (2) time frame. That request seeks documents relating to medical monitoring procedures the plaintiff has undergone in the past 10 years or anticipates undergoing—documents that go to the very heart of the medical monitoring plaintiffs' claims.

As to Plaintiffs' subject matter overbreadth objection, Plaintiffs requested that Defendants provide more examples of specific medical monitoring procedures that the request would encompass. Defendants obliged. Defendants' revised requests, attached hereto as **Ex. C**, provide the requested additional guidance as to the types of procedures for which Defendants seek documents.

As to time frame, Plaintiffs objected to the request seeking documents going back 10 years rather than to January 1, 2012. The medical monitoring Plaintiffs allege that valsartan contamination began in 2011. Dkt. 123 at ¶ 5. They also specifically exclude from the class anyone with a cancer diagnosis allegedly caused by valsartan-containing drugs. *Id.* ¶ 391. Defendants need pre-2012 records both to

ascertain whether Plaintiffs fall within the alleged class, and also to provide a baseline regarding any cancer screening the Plaintiffs were undergoing prior to their ingestion of allegedly contaminated valsartan. Further, Plaintiffs have already agreed to this 10 year time period elsewhere—10 years is the period for which Plaintiffs have authorized Defendants to collect records, and is also the period for which Plaintiffs have agreed to produce blood pressure readings (*see* Request No. 4, to which Plaintiffs have not objected). There is no basis for carving out a narrower time frame for medical monitoring documents than for all other medical records in this case.

After 9 p.m. this evening, Plaintiffs informed Defendants that Plaintiffs did not agree to Defendants' revised requests, but did not identify any objections or outstanding issues. Plaintiffs further represented that they will respond to Defendants' revised requests as quickly as they can tomorrow (November 10th). Defendants are hopeful that any outstanding issues can be resolved prior to the November 11th conference without Court intervention. If they cannot, Defendants request that the Court overrule Plaintiffs' objections and approve document requests to the putative medical monitoring class representatives in the form of issue an order approving these requests, attached as **Ex. C** hereto, and ordering all individual

putative medical monitoring class representatives to respond without objection and produce documents within 30 days of the Court's order.

Finally, during the meet and confer process, Plaintiffs asked Defendants whether Defendants would agree that the depositions for the putative medical monitoring class representatives should be staggered so as to track behind the depositions of the economic loss plaintiffs. Defendants responded that the Court's orders have been clear that the depositions of all class representatives, including medical monitoring class representatives, are to be conducted by March 26, 2021. *See* Dkt. 585 and 597. There should not be a separate, later time frame for the depositions of the medical monitoring class representatives.

(c) Third Party Payor Class Representatives

The Court has previously ruled that Defendants "have a right to serve Rule 34 document requests" because the production of information by MSPRC Recovery Claims, Series LLC ("MSP") and Maine Automobile Dealers Association, Inc. Insurance Trust ("MADA"), the two putative TPP class representatives, was not "exhaustive with regard to all of the information the defendants needed for class certification purposes." Tr. of 10-14-20 Hrg. at 32.

The parties have met and conferred and are very close to agreement as to the Rule 34 requests to be served on MADA. Defendants anticipate entering these

requests before the Court's November 11 hearing, at which time they will request that the Court issue an order approving the requests and ordering MADA to respond without objection and produce documents within 30 days of the Court's order.

The parties have also met and conferred regarding the putative TPP class representatives' responses and productions to their Plaintiff Fact Sheets ("PFSs"). MSP and MADA have agreed to produce documents that should have been included in their PFS productions and to search for additional materials that may be responsive to certain categories covered by the PFS. Thus, at issue now is whether MSP must produce information in response to Defendants' proposed document requests on behalf of all of MSP's assignors who claim to have paid for sartan-containing drugs ("SCDs").

As the Court may recall, MSP originally asserted that it was assigned claims for reimbursement for payments made for SCDs by 65 assignors, and the Court agreed that MSP could respond to the PFS on behalf of just three of those assignors (the "MSP 3"). Tr. of 10-16-19 Hrg. at 9, 18. However, in responding to the PFS, MSP produced the assignments of 94 assignors. Based on that number, during the last conference, the Court suggested that the parties consider whether responses to Defendants' document requests from a "sampling" of those 94 assignors might be sufficient. *See* Tr. of 10-28-20 Hrg. at 55. However, last week, for the first time,

Plaintiffs conceded that the actual number of assignors who have made allegedly reimbursable payments for SCDs is just 36 (the "36 Assignors").

Given that drastic reduction, and Defendants' unquestionable need for information from each of the 36 Assignors, Defendants assert that a sample is not warranted, nor would it be fair or proportionate to restrict Defendants to a sample when only 36 Assignors would have to provide discovery. In contrast, 24 consumer class representatives have (or will have) provided discovery; Plaintiffs are seeking discovery from more than 50 third parties; and Defendants have responded to more than 140 document requests and core discovery. Through MSP, the 36 Assignors seek damages in the hundreds of millions of dollars, and thus they must have more "skin in the game" than MSP's responses to document requests from just three assignors.

Critically, discovery from each of the 36 Assignors is essential to the ability of this Court and Defendants to evaluate the 36 Assignors' class action claims. Defendants' right to serve discovery covering the 36 Assignors (and MADA) is buttressed by the legal authorities cited in Defendants' prior briefs—all unchallenged by Plaintiffs' counsel—that class action defendants are entitled to use discovery devices to cut against certification (3 Newberg on Class Actions § 7:14 (2020)); that the TPPs' proposed class be readily ascertainable (*Carrera v. Bayer*

Corp., 727 F.3d 300, 308 (3d Cir. 2013)); that the TPPs' damages model must be reliably "capable of measurement on a classwide basis" (*Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013)); and that plaintiffs' proposed class must withstand the Court's "rigorous analysis" of the Rule 23 certification requirements (*In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 190-91 (3d Cir. 2020)). However, to ensure that any claimed burden from their having to respond to document requests is minimized, Defendants have reduced their number of document requests from 38 *down to eight* of the most critical categories of information needed from these TPPs.

The information requested is essential because MSP stands in the shoes of its 36 Assignors, all of whom differ materially from one another. Within the group of 36 Assignors, 10 are Medicare Advantage Organizations ("MAOs"). MAOs are private companies who offer health benefits coverage under Medicare Part C and usually include drug coverage under Medicare Part D.[1] This coverage is offered pursuant to a contract with CMS, and such plans must follow rules set by CMS. On the other hand, 26 of MSP's 36 Assignors are non-MAOs, meaning they do not offer Medicare-regulated drug coverage directly to consumers. Rather, the 26 non-MAOs

[1] *See* Medicare.gov, *Medicare Advantage Plans* (accessed Nov. 9, 2020), https://www.medicare.gov/sign-up-change-plans/types-of-medicare-health-plans/medicare-advantage-plans.

(and the nationwide class of non-MAOs they purport to represent) vary wildly in terms of, *inter alia*, their business type, products offered, benefits provided, and most importantly, potential to have even incurred any damages in connection with SCDs. Many of the non-MAOs appear to be health care providers (*e.g.*, physicians' groups, clinics, hospitals), while others (*e.g.*, Medical Consultants Management, LLC) may be managed services organizations or accountable care organizations that provide practice management and administrative support to doctors' offices. Some of the 36 Assignors have hundreds or thousands of members and six or seven-figure alleged damages, while others have one member and only a few hundred dollars of claimed damages.

Defendants' contend it is necessary to review all 37[2] TPPs' actual costs (net of rebates, fees, or other contractually arranged benefits) for SCDs, their "but for" costs of replacement blood pressure medications, and the means by which they would obtain such drugs, in order to reasonably calculate each TPP's damages (if any). These 37 separate analyses would demonstrate that the TPPs alleged damages would be far too individualized as to allow for class treatment of the TPPs. *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 260 (3d Cir. 2016) (quoting *Tyson Foods,*

[2] This number refers to MSP's 36 Assignors plus MADA.

Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1045 (2016)). Without the production of documents from each of the 36 Assignors, the Court and Defendants cannot reasonably ascertain the material similarities and differences among the TPPs. The Court and Defendants also cannot determine whether differences among the TPPs impacts the calculation of their damages. Based on the limited data obtained to date, material differences among the TPPs (MAOs, non-MAOs, and MADA) are clear. As examples:

- TPPs that are health care providers get and sell SCDs differently than MAOs or the MSP 3. Moreover, health care provider TPPs are often reimbursed by patients for drugs they dispense, which zeroes out any damages they might claim.
- In contrast to larger TPPs, smaller TPPs are more likely to be fully-insured plans that only pay monthly premiums to insurance companies in exchange for coverage of participants' drug costs. In effect, their monthly drug costs are fixed, meaning they suffered no actual damages.
- Smaller TPPs are less likely to be able to negotiate favorable pricing terms for SCDs in contrast with larger TPPs. This impacts the smaller TPPs' cost-sharing structures with patients, and to the extent cost-

sharing structures differ, smaller TPPs' net payments for SCDs would vary.

The only way Defendants can demonstrate what they believe will be insurmountable diversity and individuality among the TPPs is by obtaining and analyzing the benefits summaries, formularies, rebates, pharmacy benefits manager agreements, claims administrator agreements, and other records relating to drug costs from each TPP.

Presently, counsel for the parties remain in talks over a proposed stipulation that would address their dispute over MSP's obligation to produce documents regarding its 36 Assignors. Defendants believe additional negotiation may still result in an agreement with counsel for MSP and are hopeful that by the time of the Court's hearing, issues relating to document requests to the 36 Assignors will be resolved.

However, absent an agreement, given that Defendants' objection to class certification will likely be premised on the differences among the TPPs, it is essential that Defendants be able to collect documents reflecting those differences from each of the 36 Assignors, rather than a small sample thereof. This is especially true when the limited data collected to date are already revealing distinctions among the TPPs and the number of relevant MSP assignors has fallen from almost 100 to 36. Accordingly, absent agreement by the parties, Defendants respectfully request the

Court approve the attached document requests to be served on MADA and MSP. *See* **Ex. D** and **Ex. E**.

3. Rule 30(b)(6) Notices

On October 26, 2020, Plaintiffs served their Amended Notices of Videotaped Depositions Pursuant to Fed. R. Civ. P. 30(b)(6) to the Manufacturer Defendants (the "Notices"). On October 30, 2020, the Manufacturer Defendants served their respective responses and objections to the Notices. Each of the Notices served on the Manufacturer Defendants was between 40 and 59 topics in total, and each of the Manufacturer Defendants endeavored to respond to each topic while at the same time incorporating the Court's prior rulings on the scope of discovery—specifically, the Court's rulings at oral argument on December 11, 2019 and December 18, 2019, the Court's order filed on December 13, 2019, and the Court's order on macro discovery issues filed on November 25, 2019.

Since serving their responses and objections, each of the Manufacturer Defendants has either held or scheduled a meet and confer with Plaintiffs to review their respective responses and objections, and Plaintiffs have served second amended notices on some of the Manufacturer Defendants. The meet and confer process has been productive and is ongoing, and the Manufacturer Defendants are

hopeful that the parties will be able to continue to work together to resolve any outstanding objections without the Court's intervention.

4. Meet and Confers on Defendant Employee Deponents

The Manufacturer Defendants have engaged in initial meet and confers with Plaintiffs regarding the potential employee fact witnesses that Plaintiffs have identified for deposition. During these initial meet and confers, Plaintiffs only sought basic information such as the location of each potential deponent. The Manufacturer Defendants are ready and willing to engage in further meet and confers regarding the fact witness depositions. Plaintiffs have not yet identified the appropriate Plaintiff contacts who will be responsible for each meeting and conferring with each Manufacturer Defendant. *See* 10-2-20 Order (Dkt. 585) at ¶ 3 ("Plaintiffs shall promptly identify the person(s) who will be primarily responsible for the meet and confer sessions with each manufacturing defendant.").

5. Third Party Subpoenas

Plaintiffs have served or are attempting to serve subpoenas (the "Subpoenas") on 63 third parties (the "Third Parties"). The Third Parties are comprised of a broad range of entities purportedly involved in some way with one or more of the

Manufacturer Defendants, but in most instances have nothing to do with Valsartan.[3] Many of the Third Parties have only an attenuated relationship with any Manufacturer Defendant's production or sales of Valsartan that is off-limits under the Court's Macro Discovery Order and has nothing to do with the alleged NDMA and NDEA impurities at issue in this litigation. The meet and confer process has revealed Plaintiffs' intention for this third party discovery–to use subpoenas to circumvent the Macro Discovery Order's limits on the scope of discovery in this litigation. Moreover, notwithstanding their widely varied business functions, Plaintiffs seek 11 virtually identical categories of documents from each Third Party. Plaintiffs made absolutely no attempt to tailor those document requests to the alleged purpose for serving each Subpoena. In addition, Plaintiffs refused to provide proper notice to Defendants of the Subpoenas. For these reasons, Defendants request certain Subpoenas be quashed in their entirety, and Plaintiffs be forced to "sharpen their pencils" and narrow the scope of other Subpoenas.[4]

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[3] On November 26, 2019, this Honorable Court issued a revised macro discovery order (Dkt. 303), attached as **Ex. F** wherein it indicated that Valsartan is the sole focus of discovery at this time.

[4] Defendants note that, in accordance with the Federal Rules of Civil Procedure, all Third Parties have the right to provide their own responses and objections to their respective subpoenas, and nothing in this submission should be interpreted to in any way waive, hinder or limit those rights of the Third Parties. Furthermore, with

(a) The Subpoenas Were Served Without Proper Notice

On September 30, 2020, Plaintiffs sent Defendants a list of Third Parties they intended to subpoena, and invited Defendants to meet and confer about those entities. *See* **Ex. G**, Email from Goldenberg, 9-30-20. In response to that email, certain Defendants requested a copy of the subpoena or a list of the information Plaintiffs intended to request. *See* **Ex. H**, Email from Goldberg, 10-2-20, ("Counsel for ZHP and Solco also would like to have a call, and it would be helpful to see the draft subpoenas or the list of information you are seeking from the Third Parties in advance of the call."). However, Plaintiffs refused to provide that information unless all of the Defendants agreed to accept service of all of the Subpoenas. *See* **Ex. G**, Email from Goldenberg, 10-2-20 ("Will Defendants first inform Plaintiffs for which entities they will agree to accept service or process?"). After this exchange, and without first providing copies of the subpoenas or lists of the categories of documents to be requested, Plaintiffs purported to serve the Subpoenas on October 15 and October 16, 2020. *See* **Ex. I**. Such service violates Fed. R. Civ. P. 45(a)(1), which requires that "a notice and a copy of the subpoena must be served on each

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respect to the Subpoenas issued to the Third Parties purportedly related to ZHP, Plaintiffs have agreed that responses to the subpoena directed to Mr. Ball are due on November 22, and responses to the remaining ZHP third-party subpoenas are due on November 30.

party" "before it is served on the person to whom it is directed." For this reason alone, the Subpoenas should be stricken.

(b) The Subpoenas are Patently Overbroad and thus Seek Discovery that is Irrelevant and Disproportionate

The Third Parties are comprised of vendors, manufacturers, raw ingredient suppliers, re-labelers, repackagers, testing consultants, recall service providers, and even an attorney from the law firm of Lead Liaison and Lead Counsel, Duane Morris LLP. Despite the obvious and vast differences in the types of entities that were subpoenaed, each Subpoena seeks virtually identical categories of information via more than 45 document requests: (1) Corporate Organization; (2) Contracts; (3) Communications with relevant parties; (4) ANDA and DMF file documents; (5) Nitrosamine Contamination; (6) Recall Related Documents; (7) Quarantine and/or Destruction of products; (8) Communications with the FDA; (9) Testing Data; (10) Solvent Manufacturing, Recovery, and Recycling; and (11) Toxicology Assessments. *See, e.g.*, **Exs. J-L**, Subpoenas directed to CABB AG (raw material supplier), Return Logistics (recall provider), and Frederick Ball, Esq., attorney at Duane Morris. Most, if not all of these aforementioned categories are included in nearly every subpoena to every entity, irrespective of what type of function that entity served. For example, there is no defensible reason why a third party supplier

of a raw material starting ingredient should have received a subpoena requesting information and documents concerning Recall-Related Documents and Quarantine and/or Destruction categories. *See* **Ex. J**, CABB Subpoena. The overbreadth of the Subpoenas, which requires the Third Parties to provide information that has nothing to do with any of the facts or circumstances relating to any of the claims or defenses asserted in this litigation, violates the rule that discovery be of relevant information and proportionate to the case. *See* Fed. R. Civ. P. 26(b)(1).

(c) The Subpoenas Violate the Macro Discovery Order

The Court entered its Macro Discovery Order (Dkt. 303) on November 26, 2019, setting the parameters for discovery in this litigation. Given that Plaintiffs are U.S. consumers, who assert claims that involve only the sale of valsartan in the U.S., the Macro Discovery Order explicitly limits discovery regarding Defendants' operations in the following pertinent ways:

> Plaintiffs' request for discovery regarding other products using the same manufacturing processes, solvents, and testing as those for Valsartan API is DENIED. However, defendants shall produce all documents reflecting the presence of any nitrosamine in any sartan product. Dkt. 303 at ¶ 4.
>
> Plaintiffs' request for foreign regulatory documents is GRANTED in part and DENIED in part. Plaintiffs' request for all foreign regulatory documents sent or received regarding Valsartan and the Valsartan recall is DENIED. *Id.* at ¶ 6

> Plaintiffs' request for foreign sales, marketing materials and agreements is DENIED. *Id.* at ¶ 7.
>
> […] Plaintiffs are also entitled to discovery regarding any test that could identify the presence of nitrosamine contamination. Also, testing and results regarding other carcinogens, general toxic impurities, or residual solvents in the Valsartan API and Valsartan are relevant. *Id.* at ¶ 8.

The Court's Macro Discovery Order is the law of this case and should be followed. *See, e.g. Musacchio v. United States*, 136 S. Ct. 709, 716, 193 L. Ed. 2d 639 (2016) (law of the case doctrine generally provides that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case); *Krys v. Aaron*, 106 F. Supp. 3d 472, 480 (D.N.J. 2015). Yet, notwithstanding the above limits on discovery, the Subpoenas seek information about a wide range of Defendants' operations that extend beyond the limits set out in the Macro Discovery Order. For this reason, certain of the Subpoenas should be quashed in their entirety, as their only purpose is to circumvent the Macro Discovery Order. *See* **Ex. M**, List of Subpoenas to be Quashed. Further, Plaintiffs should be ordered to modify the other Subpoenas to preclude the circumvention of the Macro Discovery Order. *See* **Ex. N**, List of Subpoenas to Be Modified.

(d) Third Party Discovery is Governed by the Operative Confidentiality and Protective Order

Third-party discovery in this litigation is governed by the Confidentiality and Protective Order, which contemplates that the information sought by Plaintiffs'

subpoenas to the Third Parties constitutes protected information. *See* **Ex. O**, Confidentiality and Protective Order (Dkt. 139) at ¶¶ 2, 14. Specifically, the Protective Order states "[t]hird parties may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and therefore become a Producing Party and/or Receiving Party for purposes of this Protective Order." *Id.* ¶ 2. In addition, the Protective Order stipulates that all "[d]ocuments produced by a non-party must be treated by the receiving party as PROTECTED INFORMATION for a period of fourteen (14) days from receipt." *Id.* ¶ 14. Furthermore, the Protective Order expressly grants each party the right to designate PROTECTED INFORMATION produced by Third Parties within fourteen days of receipt of the third-party documents. *Id.* Despite the Protective Order's contemplation of third parties producing protected information, the danger is that the Third Parties may be unaware of the protocol established by the Protective Order, and, given the incredibly broad and all-encompassing scope of Plaintiffs' subpoenas to Third Parties, multiple Subpoenas may elicit documents containing protected information from multiple Defendants. Because the Subpoenas are so broad, it is difficult to determine whether a Subpoena directed to an entity purportedly associated with Teva, for example, will indeed only produce documents related to Teva. More than likely, given the scope of requests, the entity will produce documents containing

protected information from multiple Defendants and Defendants will then be placed in the unfair position of having to scramble rapidly to protect their information because the subpoenas were not narrowly tailored in any way. *See Schmulovich v. 1161 Rt. 9 LLC*, No. 07-597, 2007 WL 2362598, at *2 (D.N.J. Aug. 15, 2007) (citing *Thomas v. Marina Assocs.*, 202 F.R.D. 433, 434-435 (E.D. Pa. 2001)).

(e) Subpoenas to Third Parties Related to Each Manufacturer Defendant

(i) Subpoenas Served on ZHP-Related Parties Should be Quashed or Modified

Plaintiffs served or attempted to serve twenty-two Subpoenas on Third Parties purportedly having some involvement with one or more of the ZHP Parties. Of those twenty-two Subpoenas, the ZHP Parties request the Court strike eight, and order Plaintiffs to narrow the requests of the remaining fourteen.

The Court should strike Plaintiffs' Subpoenas directed to the following Third Parties purportedly connected to the ZHP Parties as listed in **Ex. M**:

1. Azbil Telstar Technologies
2. CABB AG
3. Chemo Group India
4. Linhai Huanan Chemical Co., Ltd.
5. Malvern Instruments
6. Shiva Pharmachen Pvt. Ltd.
7. Tiefenbacher API + Ingredients
8. VXL Life Sciences

In support of issuing a Subpoena to Azbil Telstar Technologies ("Azbil"), Plaintiffs rely solely on a single audit Azbil conducted on behalf of a Spanish generic drug manufacturer seeking to inspect ZHP's manufacturing processes for European Medicines Agency ("EMA") compliance. Plaintiffs have noted that the audit was coincidentally conducted at a site that produced valsartan API. Plaintiffs, however, could not identify a single finding or conclusion of that audit relating to the presence of nitrosamines in valsartan API. Accordingly, this subject matter is plainly outside the scope of the Macro Discovery Order. Dkt. 303 at ¶ 6. Similarly, Plaintiffs issued subpoenas to CABB AG, Linhai Huanan Chemical Co., Ltd., and Shiva Pharmacem, three foreign entities who were raw material suppliers for Valsartan. Again, Plaintiffs could not identify a reasonable basis or nexus to this litigation for issuing these subpoenas beyond identifying their role as suppliers of valeryl chloride (CABB and Shiva) and BBTT (Linhai), starting ingredients in Valsartan. These entities have no relationship to the question of the presence of nitrosamines in Valsartan, and the Subpoenas directed to them should be stricken.

Furthermore, Plaintiffs issued Subpoenas to Tiefenbacher API + Ingredients, a German entity, and VXL Life Sciences, an Indian company, for their involvement with API and particle size testing. Similarly, Plaintiffs claim that Malvern Instruments, a British entity, performed particle size testing for Valsartan but have

not demonstrated how this particle testing is reasonably related to sales of Valsartan in the U.S. This testing plainly falls outside the parameters on testing discovery laid out in the Macro Discovery Order. *See* **Ex. F**, Dkt. 303 at ¶ 8 (limiting testing discovery to testing that could identify the presence or nitrosamines, carcinogens, general toxic impurities, and residual solvents).

Moreover, for Chemo Group India, Plaintiffs pointed to a single email between ZHP and Chemo Group India's parent company concerning Valsartan API, on which Chemo Group India was copied. Plaintiffs have not provided any further evidence to establish any reliable connection between Chemo Group India, which appears to be an Indian subsidiary of a Spanish biotechnology company, and U.S. sales of Valsartan, as would be required for the subject matter to fall within the scope of the Macro Discovery Order.

In addition to striking the eight aforementioned subpoenas, the Court should instruct Plaintiffs to sharpen their pencils and modify the scope of all remaining third-party subpoenas associated with the ZHP Parties to ensure that they comply with the law of the case as outlined in the Macro Discovery Order. Even if the remaining Third Parties possess documents or information relevant to the litigation, the generic and all-encompassing subpoenas that Plaintiffs have served still violate Fed. R. Civ. P. 26(b)(1), which requires that discovery be limited to relevant

information and proportionate to the case. The purpose of Rule 26(b)(1) and the Macro Discovery Order is to limit discovery to facts or circumstances relating to the claims or defenses asserted in this litigation, and therefore the subpoenas directed to the Third Parties contained in **Ex. N** should be modified to eliminate those requests that have nothing to do with that entity's business operations as they relate to the subject matter of this case.

(ii) Plaintiffs' Subpoenas To Third-Parties Regarding The Aurobindo Parties Should be Quashed or Modified

Plaintiffs served or attempted to serve 11 subpoenas on third parties purportedly having some involvement with one or more of the Aurobindo entities. Of those 11 subpoenas, the Aurobindo parties request the Court quash all subpoenas or, as an alternative, quash the subpoenas directed to Meridian Consulting and ToxRox Consulting and order Plaintiffs to narrow the requests of the other 9 subpoenas for the following reasons.

Plaintiffs' subpoenas served on Meridian Consulting and ToxRox Consuluting seek documents that are protected by the attorney-client privilege and the work product doctrine. Both entities were retained by Aurobindo to assist outside counsel in response to an FDA Warning letter. Thus, correspondence between Aurobindo and the subpoenaed entities contains information including, but not

limited to, statements made by Aurobindo in search of legal advice, and legal advice provided by Meridian Consulting and ToxRox consulting. Furthermore, the work performed by these entities was in response to the legal advice sought and, thus, constitutes protected work product.

"The benefit of the attorney-client privilege extends to a corporation or other organization or association, 'which must act through agents, including [its] officers and employees.'" *Hedden v. Kean Univ.*, 434 N.J. Super, 1, 11. (quoting *Macey v. Rollins Envtl. Servs. (N.J.)*, 179 N.J. Super. 535, 540, 432 A.2d 960 (App.Div.1981)); *see also Payton, supra*, 148 N.J. at 550, 691 A.2d 321; *N.J.S.A.* 2A:84A-20(3) (defining client as "a person or corporation . . . that, directly or through an authorized representative, consults a lawyer . . . for the purpose of . . . securing legal service or advice from him in his professional capacity"); N.J.R.E. 504(3) (same). The privilege, therefore, belongs to the institution and covers confidential communications between the entity's attorneys and its employees. *Id.*

Here, any communications made between Aurobindo and Meridian and/or ToxRox Consulting are protected by the attorney-client privilege and the work product doctrine. "And while the burden of proof is on the person or entity asserting the privilege to show its applicability in any given case, *L.J. v. J.B.*, 150 N.J. Super. 373, 378, 375 A.2d 1202 (App. Div.), *certif. denied sub nom. Jacobsen v. Balle*, 75

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N.J. 24, 379 A.2d 255 (1977), there is a presumption that a communication made in the lawyer-client relationship has been made in professional confidence." *Id.* at 12. With regard to the remaining nine subpoenas[5], Aurobindo requests that these subpoenas be quashed, or, in the alternative, modified. In serving these subpoenas, plaintiffs failed to comply with Fed. R. Civ. P. 45 because plaintiffs failed to provide Aurobindo with a copy of the subpoenas prior to service in violation of Fed. R. Civ. P. 45(a). Additionally, these subpoenas seek information outside the realm of this Honorable Court's macro discovery order, thus are overbroad and in contrast with Fed. R. Civ. P. 26 and this Honorable Court's Macro Discovery Order.

Counsel for Aurobindo met and conferred with Plaintiffs' counsel last week regarding the third party subpoenas and Aurobindo's Motion to Quash and Objections in relation to said subpoenas. Aurobindo will file its affidavit of compliance with L.R. 37.1(b)(1) with respect to its Motion to Quash, as ordered by the Court. Aurobindo stands on the arguments raised in connection with its motion and hopes the parties will be able to significantly narrow any issues to present to the Court through the meet and confer process.

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[5] The remaining nine subpoenas were served on the following entities: Alcame Corporation, AXIS Clinicals, Catalent, Gibralter Laboratories, Inc., Medical Affairs Company, Novartis Pharmaceutical , Peritt Laboratories, Rising Pharmaceuticals, SDS Environmental Services, Sipra Labs Limited.

(iii) Status of Subpoenas Directed to Torrent-Related Parties

Counsel for Torrent had a meet and confer with Plaintiffs' counsel last week regarding the Third Party Subpoena directed towards Sipra Labs Ltd, a contract research organization. Torrent will not accept service on behalf of the Third Party, and stands on the aforementioned objections.

(iv) Status of Subpoenas Directed to Hetero Labs-Related Parties

Hetero Labs is currently discussing the Third Party Subpoenas with its counsel. Counsel also plan to hold a meet and confer with plaintiffs' counsel on the Third Party Subpoenas this week, after which Hereto Labs will be able to set forth more specific objections.

(v) Status of Subpoenas Directed to Mylan-Related Parties

Plaintiffs have expressed an intention of serving—or, in some instances, served without prior notice—ten subpoenas on third parties purportedly having some involvement with Mylan's valsartan. Of those ten entities, six are domestic and four are foreign. On October 29, Mylan served formal objections to these subpoenas, and the parties are presently meeting and conferring with respect to Mylan's request that Plaintiffs withdraw or modify the subpoenas. A copy of Mylan's objections are attached as **Ex. P**. To the extent the parties are unable to resolve their dispute, Mylan will raise the issues with the court in the form of a motion.

(vi) Status of Subpoenas Directed to Teva-Related Parties

Counsel for Teva has scheduled a meet and confer with Plaintiffs' counsel for tomorrow, November 10, 2020, to address the third party subpoenas and Teva's Motion to Quash in relation to said subpoenas. Following this meet and confer Teva will file its affidavit of compliance with L.R. 37.1(b)(1) with respect to Teva's Motion to Quash, as ordered by the Court. Teva stands on the arguments raised in connection with its motion and hopes the parties will be able to significantly narrow any issues to present to the Court through the meet and confer process.

6. TAR Issue

(a) Teva

Teva filed its Reply in support of the Teva Defendants' Letter Motion for Cost-Shifting and/or Further Relief Under Rule 26's Proportionality Limits on Friday, November 6, 2020. The issues are now fully briefed and Teva will be prepared to argue and address any questions on the November 11, 2020 Teleconference with the Court.

(b) Mylan

Like Teva, Mylan has reached the null set with respect to its 13 "priority" custodians and will soon be reaching the global null set for its remaining 39 custodians. As required under the ESI Protocol (Dkt. 127) at 3-4, Mylan contacted

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Plaintiffs to engage in a meet and confer prior to utilizing TAR to narrow the pool of collected documents to be reviewed. The meet and confer began on October 28, and Mylan supplied additional information in accordance with Plaintiffs' requests. Since raising the issue, Plaintiffs have been non-committal as to whether they will consider any proposal to cut off the review. Therefore, Mylan anticipates that it may be necessary to raise the issue with the Court by way of motion.

7. Clarification of Document Production Deadline

The Manufacturer Defendants' document productions are currently due on Sunday, November 29, 2020, which is the Sunday following the Thanksgiving holiday. Manufacturer Defendants seek clarification that the document productions can be served on the following business day, which is Monday, November 30, 2020.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
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